



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-1313]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request (ICR) titled "Distribution of Traceable Opioid Material Kits (TOM Kits) across U.S. and International Laboratories" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on 09/16/2022 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Distribution of Traceable Opioid Material Kits (TOM Kits) across U.S. and International Laboratories (OMB Control No. 0920-1313, expiration date 12/31/2022) - Revision - National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In response to the Health and Human Services (HHS) Acting Secretary's 2017 and ongoing public health emergency declaration on opioids, the Centers for Disease Control and Prevention (CDC) has led the development of Traceable Opioid Material Kits (TOM Kits) to support detection of emerging opioids. CDC maintains the contents of the TOM Kits based on new needs identified, in part, through the U.S. Drug Enforcement Agency (DEA) Emerging Threat Reports. For example, the DEA 2018 data indicated that fentanyl and fentanyl-related compounds accounted for approximately 76 percent of their opioid identifications.

The CDC is requesting a three-year Paperwork Reduction Act (PRA) clearance for a revision of this ICR (formerly known as "Distribution of Traceable Opioid Material Kits [TOM Kits] across U.S. Laboratories") (OMB Control No. 0920-1313). As part of the proposed revisions, CDC will be expanding its program to include a new line of TOM Kits, the Emerging Drug Panel (EDP)

Kits. For the EDP Kits, non-opioid compounds will be identified and updated by searching recent lists put out by the DEA and the Center for Forensic Science Research and Education (CFSRE). These lists provide data on all classes of drugs that were recently identified in the field and provide recommendations on which drugs should be included in testing. They are updated several times a year and keep up with the changing drug landscape in the United States. For the current round, EDP Kits will include synthetic cannabinoids, stimulants, hallucinogens, and benzodiazepines.

CDC will distribute TOM Kits through a single vendor, which will manufacture the test kits. The CDC vendor will distribute these kits to domestic laboratories, as previously approved under CDC contract. As a revision, the CDC vendor will distribute these test kits to international laboratories in partnership with the United Nations and under a separate contract with the International Narcotics Control Board (INCB) (hereafter, collectively coined the "UN"). The UN, and not the CDC, is paying the vendor to ship the kits to international requesters.

TOM Kits are not intended for diagnostic use and are free to domestic and international laboratories in the public, private, clinical, law enforcement, research, and public health domains. The CDC vendor collects both application and laboratory information on domestic laboratories when they apply for test kits. International laboratories that apply for test kits

through the UN will be directed to complete and share their laboratory information with the vendor, but not with the CDC. This information is used to prioritize which laboratories will receive kits when quantities are limited. The brief web-based surveys will allow the CDC to: (1) determine what service the recipient laboratory performs; and to (2) equitably distribute test kits based on the analysis techniques and matrices used by the recipient laboratory.

Over the past three years, CDC has received 1,472 requests from interested laboratories (approximately 490 requests per year) and has distributed 3,007 TOM Kits. Based on this experience and with the addition of EDP Kits, we anticipate that up to 600 domestic laboratories will request test kits per year. Given that each application will take six minutes, the annual time burden for 600 domestic laboratories will be 60 hours. CDC will add 20 additional annual burden hours for the international distribution of test kits. We estimate that 300 international partner laboratories will apply for test kits per year with the UN, which in turn will direct these laboratories to complete the brief four-minute survey on laboratory information on the CDC vendor website.

There is no burden on the respondents other than their time. CDC estimates a total estimated time burden of 80 hours per year.

Estimated Annualized Burden Hours

Type of	Form Name	Number of	Number of	Average
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Respondents		Respondents	Responses per Respondent	Burden per Response (in hours)
US Federal Laboratories	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60
State, Local, and Tribal Government Laboratories	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60
Private or Not-for- Profit US Institutions	Test Kit Application and Questions for US Laboratories (online)	200	1	6/60
International Laboratories	Test Kit Questions for International Laboratories	300	1	4/60

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